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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,843	03/22/2004	Gonzalo Romero-Matos	ROMERO	3027
7590 10/24/2007				
GONZALO ROMERO M		EXAMINER		
APT #2		HOFFMAN, SUSAN COE		
455 39TH AVE NORTH		ART UNIT		
SAINT PETERSBURG, FL 33703-6118		PAPER NUMBER		
		1655		
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		10/24/2007		
		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/805,843	Applicant(s) ROMERO-MATOS, GONZALO	
	Examiner Susan Coe Hoffman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed August 16, 2007 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 9 and 10 have been cancelled.
3. Claims 12-25 have been added.
4. Claims 1-8 and 11-25 are pending.
5. In the reply filed on February 5, 2007, applicant elected Group II, now claims 11-25, and capsaicin (figure 1a) for the species.
6. Claims 1-8 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 5, 2007.
7. Claims 12-25 are examined on the merits.

Claim Rejections - 35 USC § 112

Claims 12-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 12 and 19 are indefinite because they do not contain a transitional phrase such as "comprising," "consisting essentially of," or "consisting of." A transitional phrase is needed in order to determine the scope of the claim. The transitional phrase allows for either the claim to be open to unclaimed elements (i.e. "comprising"), closed to unclaimed elements ("consisting of"), or partially closed to unclaimed elements ("consisting essentially of"). Since the claims do

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not contain a transitional phrase, it is unclear if the claims are intended to be open or closed to unrecited elements. When the scope is unclear it is appropriate to interpret the scope in light of the specification (see MPEP section 2111.03). Applicant's embodiments in the specification contain ingredients other than those recited in claims 12 and 19; thus, it is reasonable to interpret the claims as being open to unrecited elements.

Claims 12 and 19 are also indefinite because it is unclear what, if any, structural limitations are being placed on the claim by the recited function. In addition, it is unclear what is represented by the "x" in the function.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 12-18, 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 12-14, 20 and 21 recite ranges for the volume of the diluent in the composition. Applicant's specification provides support for some of these volumes. Specifically, the specification teaches using various volumes of the composition (i.e. 3ml, 25ml 75ml), but many of the specific values claimed by applicant and the ranges claimed by applicant are not recited in the specification or in the originally filed claims. Thus, the volumes claimed by applicant are considered to add new matter to the claims.

Claim Rejections - 35 USC § 103

10. Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaHann (US Pat. No. 4,599,342) for the reasons set forth in the previous Office action for claims 9 and 10.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claims are patentable over the prior art because the claims no longer recite Tween 80 and ethanol. However, as discussed above, applicant's claims are interpreted to be using open claim construction which allows for the presence of unrecited elements in the claims. Thus, the presence of Tween 80 and ethanol in the reference composition does not create a patentable distinction between the prior art and applicant's claimed ingredients.

Applicant also argues that the claimed invention is patentable over the prior art because the prior art does not teach using the claimed function to determine the optimal dosage of the capsaicin for treatment of HIV. Applicant also argues that the prior art does not specifically teach using the claimed high and low volumes of infuses claimed. However, as discussed in the previous Office action, it is considered a routine optimization of parameters to determine the amount of an ingredient in a composition. Through this routine optimization, an artisan would reasonably arrive at the dosages claimed by applicant even if the artisan does not use the claimed function to arrive at these dosages. Thus, the composition taught by the prior art is considered structurally the same composition as claimed by applicant.

Applicant also argues that the composition with two different infuses is patentable because the composition is structurally designed for the administration of the capsaicin.

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However, these are considered recitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As discussed above, the prior art is considered to provide motivation for optimizing the amount of the ingredients in the composition. Thus, the prior art teaches a composition that is structurally the same as applicant's claimed composition. Therefore, the reference properly teaches the claimed invention.

11. Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ljungdahl et al. (Journal of the Neurological Sciences (1986), vol, 72, pp. 223-230) for the reasons set forth in the previous Office action for claims 9 and 10.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claims are patentable over the prior art because the claims no longer recite Tween 80 and ethanol. However, as discussed above, applicant's claims are interpreted to be using open claim construction which allows for the presence of unrecited elements in the claims. Thus, the presence of Tween 80 and ethanol in the reference does not create a patentable distinction between the prior art and applicant's claimed ingredients.

Applicant also argues that the claimed invention is patentable over the prior art because the prior art does not teach using the claimed function to determine the optimal dosage of the capsaicin for treatment of HIV. Applicant also argues that the prior art does not specifically teach using the claimed high and low volumes of infuses claimed. However, as discussed in the

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previous Office action, it is considered a routine optimization of parameters to determine the amount of an ingredient in a composition. Through this routine optimization, an artisan would reasonably arrive at the dosages claimed by applicant even if the artisan does not use the claimed function to arrive at these dosages. Thus, the composition taught by the prior art is considered structurally the same composition as claimed by applicant.

Applicant also argues that the composition with two different infuses is patentable because the composition is structurally designed for the administration of the capsaicin. However these are considered recitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As discussed above, the prior art is considered to provide motivation for optimizing the amount of the ingredients in the composition. Thus, the prior art teaches a composition that is structurally the same as applicant's claimed composition. Therefore, the reference properly teaches the claimed invention.

12. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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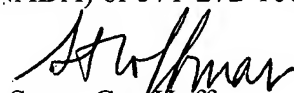
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Susan Coe Hoffman
Primary Examiner
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